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Standard test method for evaluating tibial insert endurance and deformation under high flexion

评价高屈曲条件下膝关节胫骨衬垫耐久性和变形试验方法

(English Translation)

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Standard test method for evaluating tibial insert endurance and deformation under high flexion

1 Scope

This standard specifies a test method for determining the endurance properties and deformation, under specified laboratory conditions, of ultra high molecular weight polyethylene (UHMWPE) tibial bearing components used in bicompartmental or tricompartmental knee prosthesis designs.

This standard applies to bearing components manufactured from UHMWPE.

Note: This test method could be adapted to address unicompartmental total knee replacement (TKR) systems, provided that the designs of the unicompartmental systems have sufficient constraint to allow use of this test method.

This test method does not include instructions for testing two unicompartmental knees as a bicompartmental system.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

YY/T 0772.3 *Implants for surgery - Ultra-high-molecular-weight polyethylene - Part 3: Accelerated ageing methods*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

anatomic (mechanical) axis of femur

the line between the center of the femoral head and the center of the femoral knee

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3.2

bearing centerline

the line running anteroposterior that is the mirror line of the femoral articulating surface

Note: For asymmetric bearing tibial tray designs, the appropriate tibial tray centerline shall be determined and reported along with the rationale for the location.

3.3

bearing retention mechanism

mechanical means for preventing tibial tray/bearing disassociation

3.4

femoral component centerline

a line running anteroposterior between the femoral condyles and parallel to the femoral condyles

Note: The line should be equidistant between the condyles. For asymmetric or non-parallel condyles designs, the appropriate centerline shall be determined.

3.5

fixed bearing system

a knee prosthesis system comprised of a femoral component and a tibial component, where the tibial articulating surface is not intended to move relative to the tibial tray

3.6

mobile bearing

the component between fixed femoral and tibial knee components with an articulating surface on both the inferior and superior sides

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3.7

mobile bearing knee system

a knee prosthesis system comprised of a femoral component, a tibial component, and a mobile bearing component that can rotate and/or translate relative to the tibial component

3.8

tibial axis

nominal longitudinal axis of the tibia, which corresponds with the central axis of the medullary cavity of the proximal tibia

3.9

posterior slope

the angle that the perpendicular axis of the tibial tray makes when it is tilted posteriorly away from the tibial axis (see Figure 1)

3.10

***R* value**

the ratio of the minimum force to the maximum force (that is, R = minimum force/maximum force)

3.11

tibial tray-bearing disassociation

unrecoverable physical separation of the tibial bearing and tibial tray components as a result of bearing distraction or tilting

3.12

tibial tray centerline

a line running anteroposterior that is the mirror line of the tibial articulating surface

Note: For asymmetric bearing tibial tray designs, the appropriate tibial tray centerline shall be determined and reported along with the rationale for the location.

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